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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/519,202 | 08/08/2005 | Todd M Boyce | 525400-344 | 4795 |
| 25763 | 7590 | 06/01/2009 | EXAMINER | |
| DORSEY & WHITNEY LLP | | | SHAHRESTANI, NASIR | |
| INTELLECTUAL PROPERTY DEPARTMENT | | | | |
| SUITE 1500 | | | ART UNIT | PAPER NUMBER |
| 50 SOUTH SIXTH STREET | | | 3737 | |
| MINNEAPOLIS, MN 55402-1498 | | | | |
| | | MAIL DATE | DELIVERY MODE | |
| | | 06/01/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|-------------------------------------|
| Office Action Summary | Application No. 10/519,202 | Applicant(s) BOYCE ET AL. |
| | Examiner NASIR SHAHRESTANI | Art Unit 3737 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 April 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-33,35 and 36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-33,35 and 36 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/03/2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-33, 35 and 36 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 1-13 and 30 are objected to because of the following informalities: in claim 1, “the donor bone parameters” lacks antecedent basis. Furthermore, in claim 6, a period should be inserted at the end of the claims.

Appropriate correction is required.

Claims 7, 30, and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims fail to provide a further step to the process of parent claims 1 and 14.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-29, 32-33, 35, and 36 are rejected under 35 U.S.C. 101 because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. See Diamond v. Diehr, 450 U.S. 175, 184 (1981) (quoting Benson, 409 U.S. at 70); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978) (citing Cochrane v. Deener, 94 U.S. 780, 787-88 (1876)). See also In re Bilski (Fed Cir, 2007-1130, 10/30/2008) where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-18, 20-33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (U.S. 6,458,144 B1) in view of Dore et al. (U.S. 2003/0236473 A1).

Morris et al. teach a method for manufacturing skeletal implant (see title) wherein a donor bone (element 14) taken from human or animal cadaver is provided along with evaluating the suitability of the bone and/or dowel for implant use after each step of the manufacturing process is provided (see abstract). It can be deduced that the process is done, at least, by a human user/manufacturer which is considered to be an entity capable of three-dimensional imaging, within the broadest reasonable interpretation of the claimed language, which then provides assessment and judgment on the suitability of the bone for implant based on measured parameters (col. 8 lines 12-17). Regarding claim 3, Morris et al. further teach wherein the implant configuration is marked (length marker 72) on the donor bone. Regarding claims 4 and 5, Morris et al. teach the formulation of a cutting plan (by the user/manufacturer) utilizing a cutter (dowel cutter 24) to perform the cutting into an implantable configuration. Regarding claims 6-8, the cutting plan, as mentioned before is preformed by a user/manufacturer which is clearly capable of computing. It can hence be deduced that Morris et al. teach that the cutting plan is formulated from a computer based model, being scalable and done manually. Regarding claim 33, it can be said that a user/manufacturer comprises at least a biological neural network.

Morris et al. however do not teach the use of a device which would provide a three-dimensional imaging scan of the donor bone.

Dore et al. teach high precision modeling of a body part using a 3D imaging system (see title) wherein various 3D imaging modalities such as MRI, SPECT and PET are utilized to provide data regarding cortical bone thickness for implant suitability (fig. 1), which is as indicated by the specification provided by applicant, a parameter other than overall size, for determining donor bone suitability.

It would have been obvious to one of ordinary skill in the art to have modified Morris et al. and to have provided the teaching of Dore et al. in order to provide more accurate implant assessment by using MRI, SPECT, or PET techniques.

Regarding claims 25-29, the improvement of image accuracy utilizing more advanced MRI, SPECT, PET techniques are obvious imaging improvements to those of ordinary skill in the art.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (U.S. 6,458,144 B1) in view of Dore et al. (U.S. 2003/0236473 A1) as applied to claims 1 and 5 above, and further in view of Ateshian et al. (U.S. 6,459,948 B1).

Morris et al. teach the claim limitations as described above but do not teach wherein the donor bone is cut by an automated device.

Ateshian et al. teach a method and apparatus for manufacturing prosthesis (see title) wherein automated/electronic means are provided to provide the manufacturing process (numerically controlled fabrication means 21).

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Morris et al. in view of Dore et al. and to have incorporated the automated manufacturing process of Ateshian et al. to provide for furthered accuracy in the donor bone cutting/fabrication process.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

/Nasir Shahrestani/
Examiner, Art Unit 3737

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